Amendments to the Claims

This listing of claims replaces all prior versions of claims in the application:

1. (Currently amended) A pharmaceutical dosage form suitable for oral administration [[comprising]] consisting of a molded microcellular polymeric material and a pharmaceutically acceptable active agent, and

wherein the molded microcellular polymeric material is a non-thermosetting polymerized ~~plastics~~ material comprised of at least one polyol selected from lactitol, xylitol, erythritol, sorbitol, maltitol, or mannitol, or combinations thereof; and

at least one of

a) a non-thermosetting modifier selected from a starch, maltodextrin, a dextrose equivalent, polyalditol, a hydrogenated starch hydrosylate, or a mixture thereof; and/or

b) a non-thermosetting polymer selected from carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof; and

c) optionally a sweetener, a disintegrant, a binder, a lubricant or an opacifier; and

wherein the molded microcellular polymeric material and pharmaceutically active agent form a single-phase homogeneous mixture and are injection molded into the molded microcellular ~~the~~ pharmaceutical dosage form.

2. -3. (Cancelled)

4. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at least one non-thermosetting modifier.

5. – 6. (Cancelled)

7. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the starch is pregelatinized corn starch, corn starch, potato starch, rice starch, hydroxyethyl starch, wheat starch, tapioca starch, or waxy maize starch, or mixtures thereof.

8. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the non-thermosetting modifier is a maltodextrin.

9. – 10. (Cancelled)

11. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the disintegrant is selected from croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl-cellulose, carboxymethyl-cellulose, veegum, an alginate, agar, guar, tragacanth, locust bean, karaya, pectin, or crospovidone.

12. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the lubricant is selected from glycerol monostearate, stearyl alcohol NF, stearic acid NF, colloidal silicon dioxide, silica gel, zinc stearate USP, magnesium stearate NF, calcium stearate NF, sodium stearate, cetostrearyl alcohol NF, sodium stearyl fumerate NF, or talc.

13. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the opacifier is talc USP, calcium carbonate USP, or kaolin USP.

14. (Original) The pharmaceutical dosage form according to claim 1 wherein the pharmaceutically acceptable active agent is selected from an analgesic, an anti-inflammatory agent, an anthelmintic, anti-arrhythmic, antibiotic, anticoagulant, antidepressant, antidiabetic, antiepileptic, antihistamine, antihypertensive, antimuscarinic, antimycobacterial, antineoplastic, immunosuppressant, antithyroid, antiviral, anxiolytic and sedatives, beta-adrenoceptor blocking agents, cardiac inotropic agent, corticosteroid, cough suppressant, diuretic, dopaminergic, immunological agent, lipid regulating agent,

muscle relaxant, parasympathomimetic, parathyroid, calcitonin and biphosphonates, prostaglandin, radiopharmaceutical, anti-allergic agent, sympathomimetic, thyroid agent, PDE IV inhibitor, CSBP/RK/p38 inhibitor, and a vasodilator.

15. – 19. (Cancelled)

20. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the microcellular polymeric material results in a closed cell foam.

21. (Currently amended) A pharmaceutical dosage form comprising: a rigid microcellular foam consisting of a solid excipient having voids of substantially uniform size with a maximum void dimension in the range from about 2 to 100 microns and a void fraction in the range of about 5 to 95 percent, and the solid excipient consisting of ~~comprising~~ an active pharmaceutical agent combined in a single phase homogeneous solid mixture with a non-thermosetting polymerized plastic material comprised of at least one polyol selected from lactitol, xylitol, sorbitol, erythritol, maltitol, or mannitol, or combinations thereof; and

at least one of

a) a non-thermosetting modifier selected from a starch, maltodextrin, a dextrose equivalent, polyalditol, a hydrogenated starch hydrosylate, or a mixture thereof; and/or

b) a non-thermosetting polymer selected from carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof; and

optionally ~~further comprises~~ a sweetener, a disintegrant, a binder, a lubricant, or an opacifier.

22. (Cancelled)

23. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the polyol is lactitol, erythritol or mannitol, or combinations thereof.

24. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting modifier is a starch, or maltodextrin, or a mixture thereof.

25. (Original) The pharmaceutical dosage form according to claim 24 wherein the starch is pregelatinized Corn Starch, Corn Starch, Potato starch, Rice starch, hydroxyethyl starch, Wheat starch, Tapioca starch, or Waxy maize starch.

26. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the nonthermosetting modifier is a maltodextrin.

27. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting polymer is present in an amount of 2 to 90 % w/w.

28. (Cancelled)

29. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the disintegrant is croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl-cellulose, carboxymethyl-cellulose, veegum, an alginate, agar, guar, tragacanth, locust bean, karaya, pectin, or crospovidone.

30. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the lubricant is glycerol monostearate, stearyl alcohol NF, stearic acid NF, colloidal silicon dioxide, silica gel, zinc stearate USP, magnesium stearate NF, calcium stearate NF, sodium stearate, cetostrearyl alcohol NF, sodium stearyl fumerate NF, or talc.

31. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the opacifier is talc USP, calcium carbonate USP, or kaolin USP.

32. (Original) The pharmaceutical dosage form according to claim 21 wherein the active pharmaceutical agent is selected from an analgesic, an anti-inflammatory agent, an anthelmintic, anti-arrhythmic, antibiotic, anticoagulant, antidepressant, antidiabetic, antiepileptic, antihistamine, antihypertensive, antimuscarinic, antimycobacterial, antineoplastic, immunosuppressant, antithyroid, antiviral, anxiolytic and sedatives, beta-adrenoceptor blocking agents, cardiac inotropic agent, corticosteroid, cough suppressant, diuretic, dopaminergic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin and biphosphonates, prostaglandin, radiopharmaceutical, anti-allergic agent, sympathomimetic, thyroid agent, PDE IV inhibitor, CSBP/RK/p38 inhibitor, and a vasodilator.

33- 36. (Cancelled)

37. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the microcellular polymeric material is a closed cell foam.

38. (Original) A pharmaceutical dosage form according to claim 21, in which the homogeneous solid mixture has a sufficiently high solubility in saliva that the dosage form dissolves substantially immediately in the mouth upon oral administration.

39. (Original) A pharmaceutical dosage form according to claim 21, in which the voids are in the form of closed cells.

40. (Original) A pharmaceutical dosage form according to claim 21, in which the rigid microcellular foam is enclosed within a skin having a density substantially greater than that of the microcellular foam, but having the same composition as that of said solid mixture.

41. (Original) A pharmaceutical dosage form according to claim 21, in which the overall density of the dosage form is substantially less than that of stomach fluids, whereby the dosage form is gastro-retentive.

42. to 50. (Cancelled)

51. (Previously presented) The pharmaceutical dosage form according to claim 27 wherein the non-thermosetting modifier is present in an amount of from 5 to 50% w/w.

52. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the polyol is present in an amount of from 5% to 70% w/w.

53. Previously presented) The pharmaceutical dosage form according to claim 21 wherein the polyol is present in an amount of from 5 to 50% w/w.

54. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the polyol is present in an amount of from 5 to 25% w/w.

55. (Previously presented) The pharmaceutical dosage form according to claim 1 non-thermosetting modifier is present in an amount of from 2 to 90% w/w.

56. (Previously presented) The pharmaceutical dosage form according to claim 55 wherein the non-thermosetting modifier is present in an amount of from 5 to 50% w/w.

57. (Previously presented) The pharmaceutical dosage form according to claim 1 wherein the polyol is present in an amount of from 5% to 70% w/w.

58. (Previously presented) The pharmaceutical dosage form according to claim 57 wherein the polyol is present in an amount of from 5 to 50% w/w.

59. (Previously presented) The pharmaceutical dosage form according to Claim 1 which is:

Example #	Formulation	w/w%
1	Xylitol	25%
	Hydroxypropyl cellulose, Grade EF	69%
	Croscarmellose Sodium	5%
	Glycerol monostearate	1%; or
2	Hydroxypropyl cellulose, Grade EF	90.0%
	Glycerin	7.5%
	Glycerol monostearate	2.5%; or
3	Lactitol	40%
	Maltodextrin (Maltrin M150)	50%
	Sodium Starch Glycolate	10%; or
4	Lactitol	40%
	Maltodextrin (Maltrin M150)	50%
	AcDiSol	10%; or
5	Lactitol	40%
	Maltodextrin (Maltrin M150)	50%
	Crospovidone	10%; or
6	Lactitol	45%
	Maltodextrin (Maltrin M150)	40%
	Pregelatinized Starch NF (Starch 1500)	5%
	Crospovidone	10%; or
7	Lactitol	50%
	Maltodextrin (Maltrin M150)	30%
	Pregelatinized Starch NF (Starch 1500)	10%
	Crospovidone	10%.